REMARKS

In the Office Action mailed from the United States Patent and Trademark Office on August 3, 2010, Claims 1, 5, 7, and 10-12 were rejected under 35 U.S.C. §112, as failing to comply with the written description requirement; Claims 1-12 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement; Claims 1-12 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement; Claims 1, 2, 7-10 and 12 were rejected under 35 U.S.C. §103(a) as being unpatentable over USPN 5,250,035 to Smith et al in view of USPGPub2002/0123723 to Sorenson et al; and Claims 3-6 and 11 were rejected under 35 U.S.C. §103(a) as being unpatentable over Smith and Sorenson in further view of USPGPub 2002/055715 to Young et al. Claims 1-12 are in the current application, claims 1-12 were rejected.

Rejections under 35 U.S.C. Section 112

Claims 1, 5, 1, 10-12 were rejected under 35 U.S.C. Section 112, first paragraph as failing to comply with the written description requirement. In particular the pending Action indicates that the claim language "spaced at intervals within two millimeters of each other" and "space within one millimeter of each other" has insufficient support in the specification as filed. Applicant has amended the claims as noted above and respectfully requests that the rejections be withdrawn at this time.

Claims 1-12 stand rejected under 35 U.S.C. Section 112, first paragraph as failing to comply with the written description requirement. In particular, the pending Action indicates that the claim language "structured to allow location of all of the fenestrations within a fascial compartment during injection" is not supported in the specification or the drawings as filed. Applicant respectfully notes that the specification is replete with references to an apparatus structured to allow location of all the fenestrations within a fascial compartment during injection." Page 3 of the specification indicates that "what is needed is a method for properly localizing and anesthetizing a fascial compartment containing an effected lower extremity nerve

while avoiding intravascular injection and/or inadvertent penetration of the effected nerve." Lines 19-22. Page 8 of the specification indicates that "a fascial compartment 30 containing lower extremity nerves may comprise only a few millimeters in width. For example, a discrete fascial compartment 30 with only a few millimeters is located between the semi-tendonitis muscle 32 and the bicep femorous muscle 34. The fascial compartment 30 houses the scaitic nerve 36 one of two major lower extremity nerves. Fenestrations 20 are thus preferably located within one to three millimeters, most preferably within 0.17 inches, of each other on the needle 12 to ensure that an efflux of anesthesia may be received by a particular fascial compartment 30. Lines 7-14. Page 10 of the specification provides "for example, during a peripheral nerve block procedure, an anesthesiologist rather practitioner may need to draw and reinsert the needle until he or she can verify that the needle is not located intravascularly." Lines 15-18. Page 10 also provides that "the stylet cap 62 of the present invention reduces the likelihood that an anesthesiologist or other practitioner will handle the stylet 70, thereby reducing both the incident of unnecessary trauma to tissue at the time required to complete the procedure." Lines 12-15. Accordingly, Applicant respectfully requests that the rejection to the language "structured to allow the patient of all fenestrations within a fascial compartment during an injection" be withdrawn at this time.

Claim 1-12 stand rejected under 35 U.S.C. Section 112, first paragraph as failing to comply with enablement requirement. In particular, the pending Action indicates that the difficulty of pinpointing the immediate area surrounding a peripheral nerve lacks sufficient support to enable one skilled in the art to utilize the claimed invention. The pending Action additionally indicates that a device capable of being inserted completely within the fascial compartment surrounding a peripheral nerve is not supported by the specification. Applicant respectfully submits that the specification provides for a relationship between a stylet and the needle apparatus such that selectively withdrawing the stylet from the needle apparatus enables a back flow of fluid into needle hub, from which proper localization of the apparatus may be verified prior to the administration of a local anesthetic. Specification Page 8, Lines 7-14.

Rejections under 35 U.S.C. 103

Claims 1, 2 and 7-9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No 5,250,035 ("Smith") in view of U.S. Patent Publication No. 2002/0123723 ("Sorenson"). Applicant respectfully submits that the cited references, alone or in combination, do not teach or suggest all the limitations recited in the claim set provided herein. In particular independent claims 1, 5 and 7 contain limitations drawn to a hollow needle having a plurality of fenestrations wherein the fenestrations are spaced at intervals within two millimeters of each other, wherein the needle is structured to allow location of all of the fenestrations to be located within the fascial plane during injection. The plurality of fenestrations as claimed provides the unexpected benefit of allowing a method for properly locating and anesthetizing a fascial compartment containing a nerve while avoiding intravascular injection and/or inadvertent penetration of the affected nerve. Smith's disclosure related to a spinal catheter and Sorensen's disclosure related to a method for diffusing medication in a subcutaneous injection fail to read on the peripheral nerve block needle of the present application.

One of skill in the art would not find it obvious to overcome the differences to arrive at the claimed invention. The differences between various types of needles call for differing structures and the differing structures greatly affect their suitability for differing uses. For example, using the spinal catheter system of Smith for providing a nerve block procedure would be extraordinarily difficult due to the difficulties in placing the needle outlet of Smith within the fascial compartment. Reference may be made to Smith's description of use of the cannula beginning at column 4 line 53. The procedure starts with an introducer making an initial passage or puncture that terminates adjacent the dura. (Col. 4 lines 60-64; Col. 3 lines 23-26) The system of Smith is then advanced slightly to part the dura to access the subarachnoid space. (Col. 4 lines 62-69; Col.5 lines 6-10) One of skill in the art would thus understand that the system of Smith is not properly intended for blind placement of the cannula deep within tissue, but is instead to be used for the final advancement stage just through the dura itself. This final

placement procedure is very different from the nerve block usage of the presently-claimed invention, and those differences provide significant benefits for nerve block procedures.

Similarly, the tubular medication dispersal system of Sorenson is for a very different situation than the nerve block procedure of the presently-claimed invention, and these differences are notable in the differences between the system described by Sorenson and the claimed invention. Sorenson disclosed a system for specific and anesthesia and subcutaneous diffusion and dispersion of medications along a tubular element length through disparate perforations which may be formed as striations of increasing length near the distal discharge point. Sorenson, Abstract. By contradistinction, the needle of the current invention requires fenestrations to be located proximate a distal end of the needle.

Sorenson's needle is a device directed to increasing a treatment zone by dispersing medication along the entire length of the needle, not a system as claimed in the present invention for isolating the flow of fluid to a small fascial plane. The system of Sorenson utilizes perforations or striations structured and arranged to achieve substantially-uniform volume and rate of dispersion of therapeutic fluids cylindrically along the perforated length of the tube. (Col. 3 lines 64-67; Col. 6 lines 35-37). The system of Sorenson is designed for delivery of medication subcutaneously or interstitially. (Abstract, Col. 1 lines 17-20). Thus, the system disclosed in Sorenson is designed for broad and even dispersal of the medication through the system, and one of skill in the art would understand its design as achieving this goal. Sorenson indicates that "the perforations may be uniformly dispersed with respect to each other. The perforations may alternatively be formed to be of an increasingly large in diameter or breadth at the location along the distal discharge portion approaches the distal end. And yet another alternative embodiment the perforations may be performed as striations." Sorenson, Col. 4, Lines 5-10.

At no point in Sorenson's disclosure is there a discussion of isolating fenestrations to the distal portion of the needle in an attempt to isolate the administration of an anesthetic to a discrete location while simultaneously avoiding damage to adjacent nerves or intramuscular

tissues. Rather, Sorenson indicates that "the perorations 85 desirably are structured and arranged such that each perforation provides substantially the same flow rate for each injected treatment fluid. Such an arrangement provides substantially uniform volumetric discharge of therapeutic fluids injected through lumen and into the treatment zone inside a patient." Column 5, Line 67 – Column 6, Line 7. Sorenson provides for a needle that will evenly discharge medication in a substantially uniform method along with the entire length of the needle, "such discharge more uniformly disperses medication to a treatment zone inside a patient, compared to point-force fluid introduction. Furthermore, the resulting treatment zone has a size larger than the absorption field immediately surrounding the single discharge orifice of a needle or catheter." Sorenson, Column 6, Lines 7-11. Accordingly, Sorenson's needle is a device directed to increasing a treatment zone by dispersing medication along the entire length of the needle, not a system as claimed in the present invention for isolating the flow of fluid to a small fascial plane. As indicated by Sorenson, the present invention discharges treatment fluids as a substantially uniform cylindrical pool at a treatment site inside a patient." Column 6, Lines 35-37. It should be noted that Sorenson describes the desirable size of striations to achieve this goal, indicating that the striations (shown in Figure 3 at reference number 90, shown for reference on the next page below) should be approximately 5 millimeters in length in one preferred embodiment and approximately 1 centimeter in length in the second preferred embodiment. Sorenson, Col. 7, lns 9-22. Figure 3 may be referenced to show that the striations are spaced at approximately their own length. As this is Sorenson's only teaching with respect to the size and spacing of the striations/perforations, Applicant respectfully notes that Sorenson fails to teach the claimed fenestrations spaced at intervals between one and two millimeters of each other as is required by the claims.

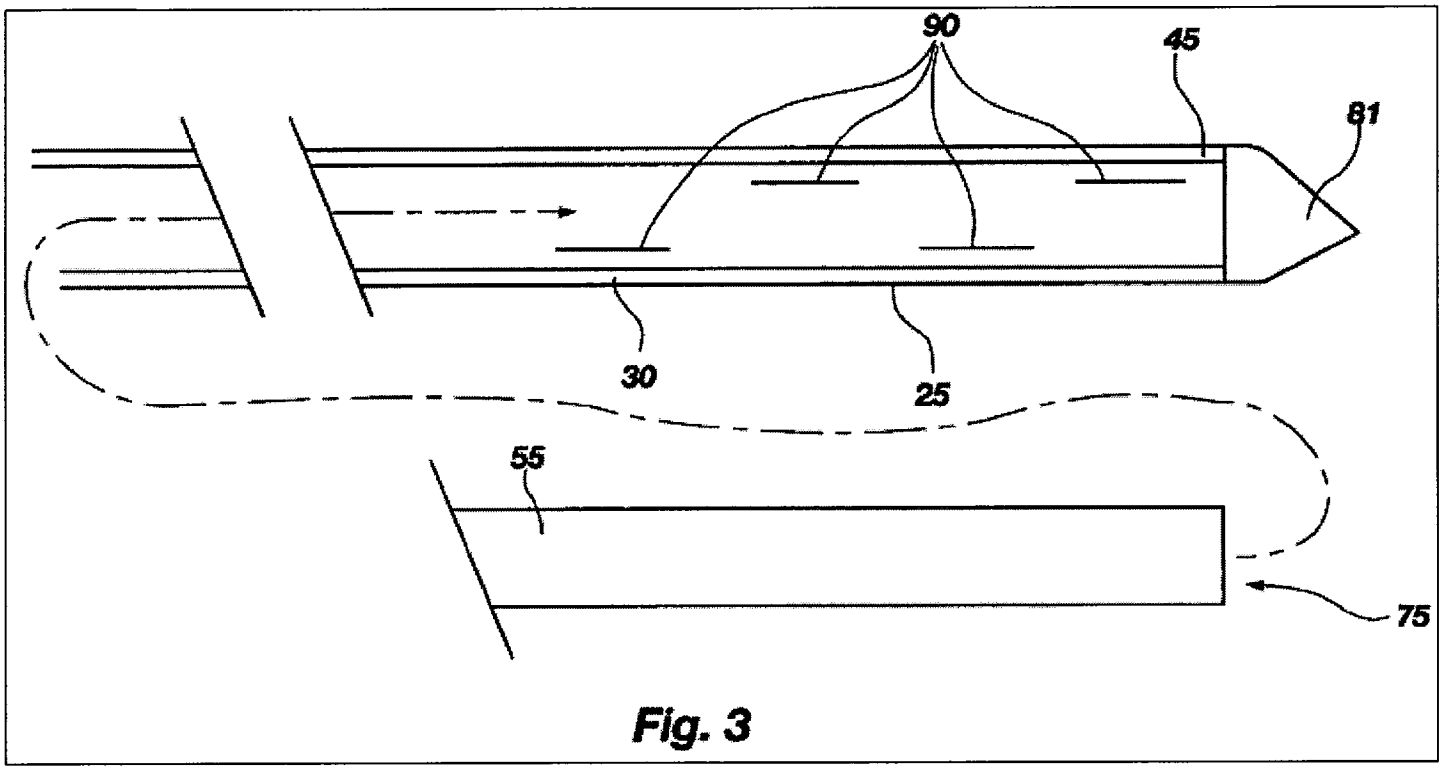

Fig. 3

Because of the different anticipated uses between the claimed invention and the devices disclosed in the cited references, one of skill in the art would not find it obvious to modify those references to change the approximately 5 millimeter spacing of Sorenson to the claimed fenestrations having spacing at intervals within two millimeters of each other. While the Sorenson device is designed to apply medicine uniformly around all the Sorenson openings, the claimed nerve block needle apparatus is designed to position all of the fenestrations within a fascial compartment (which can be very narrow). In this use, the flow through the intra-muscular fenestrations is relatively low while the flow within the fascial compartment is higher. (See specification as filed, page 8 line 18 through page 9 line 11.) If a needle having the spacing disclosed in Sorenson (for general pain medicine administration, not for peripheral nerve blocks) were used to attempt a nerve block as disclosed in the present application, the attempt would

likely fail due to the high likelihood that access to the fascial compartment would not be achieved.

Although the differences between Sorenson and the claimed invention are subtle, Applicant respectfully submits that the differences are extremely important and that one of skill in the medical arts would not find it obvious to modify Sorenson to arrive at the claimed invention. Therefore, for at least these reasons, the claims are not made obvious by the combinations of references including Smith and Sorenson.

Additionally, with respect to method claim 7, Applicant respectfully notes that none of the cited references disclose the method steps required by the claim. Specifically, claim 7 requires: "inserting a fenestrated needle into said dermal area, said fenestrated needle comprising a plurality of fenestrations, structured to allow location of all of the fenestrations within the fascial compartment during injection, wherein said plurality of fenestrations are proximate a distal end of said fenestrated needle and are spaced at intervals within two millimeters of each other," "advancing said fenestrated needle slowly through said dermal area and said fascial membrane, whereby at least one of said fenestrations is located within said fascial compartment," and "injecting local anesthetic through said fenestrated needle to induce an efflux of local anesthetic into said fascial compartment while minimizing flow of anesthetic outside the boundaries of the fascial compartment and a corresponding anesthetic block at said affected peripheral nerve." Such features are not taught by any of the cited references, which fail to disclose or discuss any features with respect to fascial compartments. Therefore, for this additional reason, method claim 7 is not made obvious by the cited references, and its dependent claims are similarly allowable.

Because the combination of art does not teach every limitation of the claimed invention, and because one of skill in the art would not find it obvious to modify the art to overcome the differences between the art and the claimed invention, Applicant respectfully requests that the obviousness rejections be withdrawn.

CONCLUSION

If any impediments to the allowance of this application for patent remain after the above amendments and remarks are entered, the Examiner is invited to initiate a telephone conference with the undersigned attorney of record.

DATED this 3 day of November, 2010.

Respectfully submitted,

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